

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/460,292	MANGELSDORF ET AL.
	Examiner	Art Unit
	Joseph T. Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to the after final amendment filed October 31, 2003.
2.  The allowed claim(s) is/are 1,2,4-13,21,23-27,29,44 and 45.
3.  The drawings filed on 10 December 1999 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

### **DETAILED ACTION**

This application is an original application filed December 10, 1999, which claims benefit to provisional application 60/111,894, filed December 10, 1998.

Applicants' after final amendment filed October 31, 2003, has been received and entered. Claims 1, 2, 21, 26, 27, 44 and 45 have been amended. Claims 3, 14-20, 22, 28 and 30-43 have been cancelled. Claims 1, 2, 4-13, 21, 23-27, 29, 44 and 45 are pending and currently under examination.

#### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Highlander on November 3, 2003.

The application has been amended as follows:

In claim 1, final line, delete [animal] and insert "mouse" therein.

In claim 44, first line, after 'A' insert "isolated".

In claim 45, first line, after 'A' insert "isolated".

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The amendment to the claims made in the after final amendment has obviated the basis of the rejections made under 35 USC 112, first and second paragraph. The Examiner's amendment was made for purposes of consistency to clearly define the control as a mouse. The present disclosure reduces to practice a transgenic mouse whose genome comprises an altered endogenous nuclear oxysterol receptor gene (LXR $\alpha$ ). The working examples in the specification demonstrate that disruption of the LXR $\alpha$  allele results in the decrease of the LXR $\alpha$  protein and said transgenic mouse quickly exhibits hepatomegaly and cholesterol accumulation when on a high cholesterol diet. Further, the phenotype of the transgenic mouse is present when only one or both alleles have been altered. The product claims have been amended to encompass a transgenic mouse with an altered LXR $\alpha$  allele consistent with the present disclosure. The claimed methods provide use of the transgenic mouse and the means to screen substances for their potential affect on cholesterol related phenotypes (claim 21) and bile acid related phenotypes (claim 27).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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JOSEPH WOITACH  
PATENT EXAMINER